KIPLEY J. McNALLY, PLC
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June 19, 2015

VIA FACSIMILE 502-564-7573
VIA E-MAIL tricia.orme@ky.gov

Ms. Tricia Orme
Office of Legal Services
275 East Main Street, 5 W-B
Frankfort, Kentucky 40602

Re: Comments on Proposed Administrative Regulations
Amendments to the 2015-2017 State Health Plan for
Facilities and Services
Hearing on June 22, 2015

Dear Ms. Orme:

On behalf of Commonwealth Eye Clinic, Inc., I am submitting written comments regarding the proposed amendments to the 2015 -2017 State Health Plan for your consideration.

COMMENTS

Paragraph 6 (b) under the review criteria for an ambulatory surgery center requires that "... outpatient surgery procedures have been performed in a private office for a period of five years prior to the date the application was submitted ...". Below find several questions, comments, and suggestions:

i. How many surgical procedures must be performed during the five year period?

ii. Could it be as little as two procedures in a five year period?

iii. The review criteria should require that a minimum number of outpatient surgery procedures be performed in a physician's office on a regular and a continuous basis.

iv. Criteria 6 (a) requires that the private office be organized and in continuous operation in Kentucky for a period of ten years prior to the date the application is submitted. However, review Criteria 6 (b) does not have any requirements for the regular and continuous performance of surgical procedures in the physician's office during the five year period.

v. A mobile laser (i.e., a "roll on, roll off" unit) or mobile operating facility can be rented for a day at a time. Can a mobile operating facility and surgical equipment qualify for Criteria 6 (b) that surgery procedures be performed in a private office of a physician?

vi. Can a mobile truck with surgical facilities be set-up in the parking lot of the physician's office to meet the review criteria?

vii. Will a CON, if granted, be limited to the actual surgical procedures performed in the physician's private office during the five (5) year period that are submitted in the application to satisfy the review criteria?

viii. Will the CON be limited to at least the surgical procedures the physician is duly licensed/Board Certified to perform?

ix. Will there be any restrictions on the transferability of the facility granted a CON and subsequent license to operate under the physician office criteria? Will transfers be restricted to a new physician office that satisfies the review criteria? Will such restrictions be placed on the certificate issued to the applicant?

x. The review criteria does not require any demonstration of financial feasibility. An unprofitable facility is more likely to take actions to minimize costs, which may adversely affect patient safety. How is patient safety going to be ensured if there is a proliferation of new surgical facilities competing for the same patients?

xi. The CON applications currently on file, and deferred in the most recent newsletter have Project Costs ranging from a low of $500,000.00 to a high of $9,286,900.00, with an average of $6,354,962.00 for seven (7) applications. Unless, the applicant demonstrates that the applicant has a sufficient volume of cases to pay for the initial investment, and ongoing operating costs, the applicant should not be granted a CON.

xii. What level of review will such applications receive—non-substantive review?

xiii. Will the physician office be allowed to partner/contract with a non-physician owned surgical company on the pretext that it is a management company?

If you have any questions in regard to these comments, please call or write.

Sincerely,

Kipley J. McNally

Kipley J. McNally

KJM:jlr

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June 29, 2015

VIA FACSIMILE 502-564-7573
VIA E-MAIL tricia.orme@ky.gov
VIA FIRST CLASS MAIL

Ms. Tricia Orme
Office of Legal Services
275 East Main Street, 5 W-B
Frankfort, Kentucky 40602

Re: Supplemental Comments on Proposed Administrative Regulations
Amendments to the 2015-2017 State Health Plan for
Facilities and Services
Hearing on June 22, 2015

Dear Ms. Orme:

On behalf of Commonwealth Eye Clinic, Inc., I am submitting supplemental written comments regarding the proposed amendments to the 2015 -2017 State Health Plan to 900 KAR 5:020. By letter dated June 19, 2015, the undersigned submitted an initial set of written comments to you for consideration. The previously submitted comments will not be repeated in this letter.

SUPPLEMENTAL COMMENTS

Under Section 6 (e) of the review criteria for an ambulatory surgery center, the applicant must document that an ambulatory surgical center is accredited by one of four listed accrediting organizations. Below please find several questions, comments and suggestions:

i. The review criteria in Section 6(e) violates KRS §13A.224 because another state regulation "... sets forth a comprehensive scheme of regulations of the subject matter; ..."

ii. The review criteria in Section 6(e) violates KRS §13A.2245 because section 6(e) incorporates the accrediting standards of the listed organization regarding subject matter which is subject to an existing comprehensive scheme of state regulations.

iii. The review criteria in Section 6(e) violates KRS §13A.120 because the administrative body is not authorized by statute to delegate the subject matter to another organization when the Division For Licensing and Regulation in the Office of the Inspector

General has been delegated licensure responsibility for facility specifications for construction, alteration and maintenance of ambulatory surgical centers.

iv. The review standards of the four listed organizations are established by said organization at their discretion. From time-to-time, any one of these organizations will change their review standards. Each organization's review standards may be less stringent than the applicable state standards set forth in regulations by the Division for Licensing and Regulation in the Office of the Inspector General.

v. The potential for changing/altering the review standards by the listed organizations violates the due process and equal protection rights of the citizens of the Commonwealth of Kentucky guaranteed by both the Federal and Kentucky Constitutions because citizens are not provided reasonable notice of what actions are expected, or what action must be refrained from.

vi. Granting, via administrative regulation, the sole accrediting authority to these four private organizations is contrary to federal anti-trust laws and violates Kentucky's model procurement code.

If you have any questions in regard to these questions, comments and suggestions, please call or write.

Sincerely,

Kipley J. McNally

Kipley J. McNally

KJM:jlr

COLORECTAL SURGICAL & GASTROENTEROLOGY ASSOCIATES, P.S.C.
Drs. John Fox, David Svetich, Charles Papp, John Dvorak, Bruce Belin & Jennifer Rea
Drs. Stephen Schindler, Nathan Massey, Thomas Knopp
2620 Wilhite Drive
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Colorectal Dept - 859-278-6031 Gastroenterology Dept - 859-278-8486

TELECOPY TRANSMITTAL COVERSHEET

Fax 859-277-7015

Attention: Tricia Orme Fax: 502-564-7573

From: Dr Jennifer Rea

Regarding: 900 KAR 5:020

Date: 6-25-15 # of pages (including coversheet): 3

Please call if you have any questions.

THANKS!

IF YOU DO NOT RECEIVE ALL OF THE PAGES OR HAVE ANY PROBLEMS WITH THIS TRANSMITTAL, PLEASE CALL 859-278-6031. Please return to the above fax or call the above number if you received this confidential fax in error. THANK YOU!

Jennifer D. Rea, MD
Colorectal Surgeon
Colorectal Surgical & Gastroenterology Associates
2620 Wilhite Drive
Lexington, KY 40503

June 24, 2015

Tricia Orme
Office of Legal Services
275 East Main Street 5 W-B
Frankfort, KY 40601

RE: Proposed Amendment to 900 KAR 5:020 State Health Plan for Facilities and Services

Dear Tricia Orme:

Thank you for the opportunity to follow-up in writing after the hearing last week regarding proposed amendment to 900 KAR 5:020 State Health Plan for facilities and services. I fully support this amendment as written and as it pertains to Ambulatory Surgery Centers (ASCs) owned by private physician groups (Criteria #6).

There is a need for lower cost endoscopy service access in Kentucky. Not offering a Certificate of Need (CON) to ASCs that have a proven track record of financial sustainability, high quality and low cost, is similar to saying there is no need for affordable housing because there is an excess of million dollar mansions for sale. With so many more high deductible insurance plans these days, it is unfair to patients not to allow better access to more affordable ASCs for their life-saving procedures, such as screening colonoscopy.

As I stated at the hearing, I am a new physician recruited to Kentucky from outside of the State. I trained at top programs and was top of my class. This amendment would provide physician groups centered around serving their local communities the much needed resources to not only recruit, but keep in practice, top-notch doctors who are dedicated to providing these much needed services to the citizens of Kentucky. Otherwise, most of these physicians will go to work for large corporate entities and the sustainability of the physician-run ASC will be lost.

There was mention at the hearing about opposition from current ASCs in regards to possible cherry-picking of better paying cases away from the current ASCs. There is already cherry-picking of better paying patients at the ASCs that currently have a CON. They already discriminate among payors and cherry-pick patients in those centers. This amendment would not affect case-mix for inpatient care at all. Our group, while not having a CON, has contracts with the county health departments and the VA. This further exemplifies the benefit to the community that expanding the CON as proposed will make available to more Kentuckians.

In addition to offering high quality, low cost endoscopy services, our ASC, which currently does not have a CON, offers procedures that other ASCs with CONs and even hospitals do not. One life-saving procedure is a stool transplant. While this may seem like a very unpleasant concept at first thought, the procedure cures a very serious infection of the colon. This highlights how expanding the CON to reputable, well-established, accredited ASCs would modernize the CON process in a way that would save lives.

To further highlight why expanding the CON to well-established physician groups is good for the citizens of Kentucky, I would like to highlight that it will likely raise the bar for quality and cost-effectiveness for ASCs that have a CON currently. This will further save money for patients, the state, and the federal government. For example, our ASC is one of only 2 centers in the state and the only one in Central Kentucky that has been recognized by the ASGE (American Society for Gastrointestinal Endoscopy) for being an Endoscopy Center of Excellence in Quality and Safety. High quality competition will be a good thing for the healthcare marketplace in this state.

In summary, I fully support the proposed amendment to modernize the current CON process as written and as it pertains to ASCs owned by private physician groups. It just makes sense.

Sincerely,

Jennifer D. Rea, MD

Points in Favor of the Proposed Revisions to the 2015-2017 State Health Plan

As a private physician I would like to commend the Cabinet for Health and Family Services for developing the proposed changes to the State Health Plan, specifically Article 6 that concerns a physician or physician group. Our group as well as several other groups in the state provides cost effective high quality ambulatory surgical services in our offices. The current CON process makes it nearly impossible for these practices to obtain a CON. In 2013 the CHFS commissioned Deloitte Consulting to conduct a health care facility capacity study to evaluate the Commonwealth's facility capacity through 2017 in light of the many changes that have occurred in health care. The study found the national use rate for outpatient surgery is 56% higher than the Kentucky rate, and ambulatory surgical facilities in Kentucky are already seeing high utilization. There is not enough ambulatory surgical capacity in Kentucky.

Currently there are a small number of physician practices that have high quality, JCAH accredited, outpatient surgery centers that are built to state standards. Because they cannot obtain a CON they cannot assist in providing surgical services to Medicaid, Medicare, and the current programs available though the Affordable Care Act. As time goes by it is very likely many more Kentuckians will join these or other state sponsored programs. This will severely limit the number of patients these centers will be able to care for and cause these physician owned surgery centers to close their doors and lay off the nurses and skilled technicians they employ. This will only exacerbate the shortage in outpatient services predicted by the Deloitte study.

Article 6 in the proposed changes wisely addresses this problem. It would allow the few practices that meet the proposed standards access to a CON. These facilities are already functional and would immediately have the ability to assist in tackling the significant need for outpatient surgical services in the Commonwealth. Utilizing these centers would significantly decrease costs, save the State money, and improve heath care access to its citizens. My associates, our 73 employees and I strongly urge the Cabinet to approve article 6 of the proposed revisions of the State Health Plan.

Sincerely,
Charles Papp, M.D.
2620 Wilhite Drive
Lexington, Kentucky
40503
859 278-6031

CSGA
Colorectal Surgical & Gastroenterology Associates

David J. Svetich, MD
Charles L. Papp, MD
John T. Dvorak, MD
Bruce M. Belin, MD
Stephen P. Schindler, MD
Nathan H. Massey, MD
Thomas C. Knopp, DO
Jennifer D. Rea, MD
John M. Fox, MD, Emeritus

June 28, 2015

Dear Committee Members,

Thank you for the attention you are giving this crucial legislation aimed at providing Commonwealth residents more flexibility in their health care while having the bonus of saving them important copay dollars. I strongly support the proposed amendment to 900 KAR 5:020 State Health Plan for Facilities and Services. Naturally, this means a cost-savings to the State of Kentucky as well.

The wording of the amendment specific to CON is excellent in that it will allow only long-standing, quality-proven, accredited, physician-owned practices to obtain a CON. I assure you, CSGA will be able to better serve those that need it most by having a Certificate of Need for our office.

Sincerely,

David J, Svetich, M.D., F.A.C.S

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CSGA
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Nathan H. Massey, MD
Thomas C. Knopp, DO
Jennifer D. Rea, MD
John M. Fox, MD, Emeritus

June 29, 2015

Dear Ms. Orme,

I strongly support the proposed amendment to the 900 KAR 5:020 State Health Plan for facilities and services in regards to changes made to the process of obtaining a CON for an ambulatory surgery center concerning a private physician office or a physician group. In 2013 the CHFS commissioned Deloitte Consulting to conduct a health care facility capacity study to evaluate the Commonwealth's facility capacity through 2017 in light of the many changes that have occurred in health care. The study found the national use rate for outpatient surgery is 56% higher than the Kentucky rate, and ambulatory surgical facilities in Kentucky are already seeing high utilization. There is not enough ambulatory surgical capacity in Kentucky.

This amendment effectively addresses this issue by allowing the few already qualified, functioning physician-owned ambulatory surgery centers to obtain a CON. This opportunity would provide tremendous benefit to the Commonwealth.

- These centers will already have the certification of the most stringent accrediting agencies, the same agencies that current state licensed surgery center strive to obtain.
- While providing more ambulatory care resources, this amendment will not create a deluge of new ambulatory surgery centers. The wording in the amendment carefully delineates specific qualifications such that there are not more than a few physician run centers that qualify. This would allow the CON process to keep its goal to prevent the proliferation of health care facilities.
- By providing a CON there is now the ability to apply for a state license. This will ensure that the centers meet state standards.
- These newly licensed centers will now be able to contract with Medicare, Medicaid, and the programs formed by the Affordable Care Act including ACO's and the State Health Exchanges. Currently unlicensed centers are unable to contract with these entities confounding the shortage in ambulatory care. This will only become worse as more people qualify or opt for state run programs.

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- Our physician-owned center provides high quality care at a much lower price than commercial centers. This provides cost savings for the Commonwealth including the patient, health insurer and the State. As the cost of health care continues to climb this would be one area that would buck the trend.

My associates and I are very pleased that the Office of Health Policy filed this proposed amendment. It is well crafted and addresses a critical need regarding the delivery of health care in the state of Kentucky.

Sincerely,

Charles Papp, M.D., F.A.C.S

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CSGA
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Nathan H. Massey, MD
Thomas C. Knopp, DO
Jennifer D. Rea, MD
John M. Fox, MD, Emeritus

6/29/15

Dear Committee Members:

I write to you in support of the proposed amendments to 900 KAR 5:020 State Health Plan for Facilities and Services. My partners and I believe strongly that this amendment will modernize the certificate of need, while still keeping the cost and quality of patient care at the forefront.

The amendments to the Plan are excellent in that they open a window of opportunity for only practices that currently serve a need in the community and have proven, over a significant time period, the highest standards of quality as verified by the same credentialing bodies used by hospitals. The amendment prevents non-accredited and newly operating groups from obtaining a CON for any procedures unless they have performed these for five years. It is my opinion that these restrictions will allow very few practices this opportunity, which will clearly not hurt the hospitals or other licensed ASCs in any way.

My practice, CSGA Endoscopy Center, currently performs endoscopy procedures at nearly half the cost of other facilities; however, we are unable to serve the ever-growing Medicaid and Medicare population due to not having a CON. With a CON our goals to provide the highest quality care at a reasonable price is exactly what the Affordable Care Act is trying to accomplish. We currently contract with the local health departments and were chosen by Governor Beshear as the contracted center for the colon cancer screening grant two years in row. There is definitely a growing need in the state, and we need highly qualified centers, that are low cost, to serve the need.

Again, I strongly support the proposed amendments to 900 KAR 5:020 State Health Plan for Facilities and Services as this is clearly a powerful stance in support of enhancing the well-being of the citizens of Kentucky.

Sincerely,

Nathan Massey, MD.

2620 Wilhite Drive, Lexington, KY 40503 www.csgaky.com 859-278-6031, 859-278-8486

Dear Committee,

I am writing as a physician in support for the recently proposed changes to the CON requirements for physician offices as outlined in the proposed regulation change to the state health plan. I am a member of a well known group of physicians (colorectal surgeons and gastroenterologists) in Lexington who have been doing in office endoscopy procedures and minor anorectal surgery for the past 13 years. We strongly believe that this has saved hundreds of thousands of dollars per year for patients and insurance companies alike and also has saved many lives by enabling care to those who otherwise would have gone without.

This amendment will allow for strong established groups of physicians who have had a long track record of outstanding patient care in Kentucky to continue to adapt their practices to the ever changing health environment brought about by the Affordable Care Act. Without this change physician groups like ours will struggle and ultimately may have to close if the playing field is not changed to allow us to have an equal footing. These proposed changes to the CON law will allow us to continue providing top notch care to our patients while also keeping costs down for patients and their insurance companies.

By allowing this amendment to the state health plan go through there is no risk that this will open the doors to allow others to follow suite as the wording of this amendment is such that it applies only to current physician practices who have been in practice performing these procedures for 5 years and are certified by a qualified national certifying body. In my estimation from previous experiences in the state of Kentucky there may be 2-5 other such groups that meet all these criteria. Passing this amendment will not open the flood gates to others so the impact will be minimal.

I strongly believe that this amendment is good for the state and for Kentuckians. My hope is that the state will follow the private insurance companies in their discovery that using our group for their endoscopy and minor surgical procedures has been a good thing for them saving them hundreds of thousands of dollars a year. This amendment will allow us to continue providing high quality of care for our patients at a decreased cost.

Sincerely,

John Dvorak MD, MS, FACS, FASCRS

June 29, 2015

Tricia Orme
Office of Legal Services
275 E. Main St. 5 W-B
Frankfort, KY 40601

RE: 900 KAR 5:020
2015-2017 State Health Plan

Dear Ms. Orme:

I am writing on behalf of Paducah Ophthalmology ASC, a licensed ambulatory surgical center in Paducah, to comment on statements made by David Hoffman, the administrator of a Paducah ophthalmology practice at the public hearing on the proposed 2015-2017 Kentucky State Health Plan. I understand that Mr. Hoffman, who also is married to the owner of that practice, suggested that the Cabinet expand its proposed changes in the ambulatory surgical center review criteria to provide that ophthalmology practices seeking approval of an ASC would not be limited to procedures previously performed in their offices.

Mr. Hoffman requested that there be a "very discreet exemption" for ophthalmologists to establish a single specialty ASC to purchase "technology" that hospitals and ASCs refuse to purchase. The specific technology that he stated was not currently available in the Paducah area was a Femtosecond laser for cataract surgery.

We have operated an ASC in Paducah for twenty-five years. We have been accredited by AAAHC since we opened in 1990. We have been very responsive to the needs of patients in the Paducah area. Our ASC has purchased and operates the exact laser technology owned by Dr. Barbara Bowers that is mentioned by Mr. Hoffman in his comments. This is costly equipment, but we made the substantial investment to make this service available to patients who choose this option. Others throughout Kentucky have done the same.

There is absolutely no need to establish another ASC in the Paducah area in order to duplicate this expensive equipment. In addition, our ASC, is strictly dedicated only to eye surgery and has multiple operating surgeons. We have a Quality Assurance Committee that monitors the quality of the patient's surgery and care. We would be concerned that no such committee would be present to oversee the quality of patient care in a single-surgeon office based facility. Therefore we oppose this suggested change.

Thank you for the opportunity to comment on this proposal.

Sincerely,

Mark Gillespie, M.D.
MG/mh

100 MEDICAL CENTER DRIVE • PADUCAH, KENTUCKY 42003 • 270-442-1024

The Eye Surgery Center of Paducah

JEFF JOHNSON, M.D. • TED BORODOFSKY, M.D. • MARK GILLESPIE, M.D. • CARL BAKER, M.D.
JEFF TAYLOR, M.D. • RON TILFORD, M.D. • LANDEN MEEKS, M.D.

Michael E. Fletcher, M.D., PLLC
3176 Manor Hill Drive
Independence, Kentucky 41015

June 30, 2015

Ms. Diona Mullins
Office of Health Policy
Cabinet for Health and Family Services
275 East Main Street, 4W-E
Frankfort, Kentucky 40621

Re: Comments Regarding Certificate of Need Review of Ambulatory Surgery Centers Operated in Conjunction with Behavioral Health Services Organizations

Dear Ms. Mullins:

I am writing to formally comment upon the Update to the 2015-2017 State Health Plan ("SHP"). I respectfully request that ambulatory surgery centers ("ASCs") which will be operated in conjunction with behavioral health services organizations ("BHSOs") be excluded from the 2015-2017 State Health Plan for the reasons detailed below. I propose that the following language be added to the Ambulatory Surgery Center Review Criteria provisions of the State Health Plan:

> 7. Notwithstanding criteria 1 and 2, an application to establish an ASC shall be consistent with this Plan if the applicant is a behavioral health services organization licensed pursuant to 902 KAR 20:430.

I. The Exemption of ASCs Operated in Conjunction with BHSOs Will Improve the Quality of and Access to Behavioral Health and Substance Use Disorder Treatment.

The purpose of the Certificate of Need ("CON") Program is to improve the quality of and increase access to health care facilities, services, and providers to create a cost-efficient health care system for the citizens of the Commonwealth.[1] The exemption of ASCs operated in conjunction with BHSOs from the 2015-2017 State Health Plan will fulfill the purpose of the CON Program and better serve the health needs of Kentuckians by improving the quality of and increasing patients' access to interventional pain procedures and behavioral health care in the most cost-effective manner possible.

[1] KRS 216B.010.

Because pain and addiction are interrelated[2], the treatment of a substance use disorder experienced by a patient who suffers from chronic pain also requires appropriate treatment of the underlying pain. When left untreated, "pain may be a risk factor for relapse for individuals with addiction in remission".[3] Meanwhile, "exposure to opioids in chronic pain patients with a history of [substance use disorder] puts them at risk for opioid abuse and/or relapse."[4] Therefore, for patients with chronic pain and co-occurring substance use disorder who are at a higher risk of misusing opioids prescribed to treat their pain[5], interventional pain procedures offer a valuable, and often life-saving, treatment alternative.

Defined as "the discipline of medicine devoted to the diagnosis and treatment of pain related disorders principally with the application of interventional techniques in managing subacute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatment"[6], interventional pain management surgeries are minimally invasive[7] and avoid many of the side effects, including addiction and dependence, of prescribed opioids. Surgeries such as facet joint injections, nerve blocks, neuroaugmentation, implantation of implantable drug delivery systems for chronic pain, movement disorders and psychiatric conditions, kyphoplasty, and percutaneous spine fusion treat patients' chronic pain directly at the source without reliance upon opioid medications to which patients may become or remain addicted or dependent.

The current exclusion of ASCs operated in conjunction with BHSOs in the State Health Plan restricts access to interventional pain management services and thus increases the need for opioid prescriptions to alleviate patients' chronic pain. Increased availability of interventional pain management services will aid the recovery of patients suffering from substance use disorders by providing an alternative treatment for chronic pain that minimizes or excludes the prescription of opioids to patients who are addicted or dependent, as chronic opioid therapy is not recommended for patients with active substance use disorders.[8] Further, "[f]ewer than 20% of chronic pain patients benefit from opioids".[9] Pain and substance use disorder treatments are most effective when

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[2] "Pain Management in Patients with Substance-Use Disorders", Valerie Prince, Pharm.D. FAPHA, BCPS, American College of Clinical Pharmacy, PSAP-VII (2001), p. 171.

[3] "Management of chronic pain with chronic opioid therapy in patients with substance use disorders", Yu-Ping Chang and Peggy Compton, Addict. Sci. Clin. Pract. 2013, 8(1):21, attached as **Exhibit A**.

[4] Id.

[5] See "Prescription Opioid Abuse in Chronic Pain: A Review of Opioid Abuse Predictors and Strategies to Curb Opioid Abuse", Nalini Sehgal, MD, Laxmaiah Manchikanti, MD, and Howard S. Smith, MD, Pain Physician Journal, Opioid Special Issue July 2012, 15:ES67-ES92, p. ES67.

[6] The National Uniform Claims Committee, Specialty Designation for Interventional Pain Management – 09, <http://www.cms.hhs.gov/transmittals/Downloads/r1779b3.pdf>.

[7] Medicare Payment Advisory Commission, "Report to the Congress: Paying for interventional pain services in ambulatory settings", Washington, DC: MedPAC, December 2001, <http://www.medpac.gov/publications/congressional_reports/dec2001PainManagement.pdf>.

[8] "Management of chronic pain with chronic opioid therapy in patients with substance use disorders", Yu-Ping Chang and Peggy Compton, Addict. Sci. Clin. Pract. 2013, 8(1):21.

[9] "Opioid REMS Role Debated as Heroin Overdoses Spike", Rosemary Frei, MSc, Pain Medicine News, Volume 13(6), June 2015.

provided comprehensively, and "it is critical to ensure that [substance use disorders] continue to be addressed while treating chronic pain".[10]

The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 ("MHPAEA") requires group health plans and health insurers to ensure that financial requirements and treatment limitations applicable to mental health or substance use disorder benefits are no more restrictive than the requirements or limitations applied to medical benefits.[11] The Patient Protection and Affordable Care Act ("PPACA") has extended this mandate by requiring that any health plan provide mental health and substance use disorder services, including behavioral health treatment, as part of its essential health benefits package.[12] Because interventional pain management is critical to the comprehensive treatment of substance use disorders caused or furthered by the use of prescribed opioids, it is incumbent upon the Cabinet to ensure that access to interventional pain procedures in an ASC operated in conjunction with a BHSO is unrestricted and is equal to that of generally covered medical benefits.

Kentucky has responded to the federal mandate for behavioral health and substance use disorder treatment coverage by creating a number of provider categories aimed at addressing the Commonwealth's great need for mental health services. Among these categories, the BHSO is uniquely suited to provide a wide array of behavioral health and substance use disorder services through a variety of practitioner types appropriately trained and qualified to comprehensively address a patient's substance use disorder and behavioral health needs.[13] A BHSO which operates or utilizes an ASC for the provision of interventional pain procedures has the opportunity to treat a patient's underlying pain without reliance on a prescribed opioid to which the patient may be addicted or dependent.

Because of its breadth of staff and services, a BHSO can easily incorporate high quality interventional pain management into its care model, which would greatly increase the opportunity for success in the treatment of substance use disorders in patients with chronic pain. Such care is most effectively provided through a variety of "substance abuse treatment providers willing to collaborate on providing care to patients with comorbid pain and [substance use disorder(s)]".[14] This high level of care coordination for behavioral health and substance use disorder patients suffering from chronic pain will greatly improve the quality of and access to health care services within the Commonwealth, in furtherance of the CON Program's mission.

II. Interventional Pain Procedures Provided in an ASC Address the Underlying Causes of Substance Use Disorders At a Low Cost.

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[10] Id.
[11] 29 C.F.R. § 2590.712.
[12] 42 U.S.C. § 18022(b)(1)(E).
[13] See 902 KAR 20:430.
[14] "Management of chronic pain with chronic opioid therapy in patients with substance use disorders", Yu-Ping Chang and Peggy Compton, Addict. Sci. Clin. Pract. 2013, 8(1):21.

By eliminating or minimizing the use of opioids to which patients suffering from chronic pain may be dependent or addicted, interventional pain procedures are a critical component of behavioral health care. The ability of a BHSO to provide interventional pain procedures in conjunction with its other services and in coordination with a patient's overarching care plan allows Kentucky behavioral health and substance use disorder providers to "treat, support, and encourage individuals with a substance use disorder, mental health disorder, or co-occurring disorder to achieve and maintain the highest possible level of health and self-sufficiency".[15]

Because interventional pain procedures are considered minimally invasive and can be routinely provided to patients in an outpatient setting, ASCs are well-designed for the provision of interventional pain management. In addition to ensuring the appropriate staff, space, and equipment for high quality interventional pain management, the costs associated with the use of an ASC for such services are demonstrably lower than those for services performed elsewhere. For example, ASC usage in 2011 resulted in a 43% Medicare savings.[16] Further, multiple studies have shown that the opening of an ASC does not negatively impact hospital surgical output.[17] By providing BHSOs the opportunity to operate or utilize an ASC to increase the number of services available to address patients' behavioral health and substance use disorder needs, the Cabinet will increase access to and lower the cost of federally mandated behavioral health services.

The inclusion of the narrow category of ASCs which are operated in conjunction with BHSOs from the 2015-2017 State Health Plan would provide access to high quality and comprehensive treatment of behavioral health and substance use disorders to citizens of the Commonwealth, consistent with the goals of the CON Program and federal and state law. Accordingly, I request the Cabinet's consideration of this important matter. Thank you for your attention, and please do not hesitate to contact me with any questions or requests for additional information.

Sincerely,

Michael Fletcher

MICHAEL FLETCHER, M.D.

Z:\Fletcher, Michael, MD\SHP Comment on letterhead.docx

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[15] 902 KAR 20:430.

[16] "Ambulatory Surgery Centers and Interventional Techniques: A Look at Long-Term Survival", Laxmaiah Manchikanti, MD, Allan T. Parr, MD, Vijay Singh, MD, and Bert Fellows, MA, Pain Physician Journal, March/April 2011, 14:E177-E215, p. E206.

[17] Id.

EXHIBIT A

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Management of chronic pain with chronic opioid therapy in patients with substance use disorders

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Abstract

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Substance use disorders (SUDs), whether active or in remission, are often encountered in patients with chronic nonmalignant pain. Clinicians are challenged when managing chronic pain while facing substance abuse issues during the course of chronic opioid therapy (COT). Further, the interrelated behavioral symptomatology of addiction and chronic pain suggests that if one disorder is untreated, effective treatment of the other in not possible. Incomplete understanding of the overlapping presentations of the two disorders, coupled with insufficient management of both conditions, leads to undertreated pain and premature discharge of SUD patients from pain treatment. In order to achieve pain relief and optimal functionality, both conditions need to be carefully managed. This paper reviews the prevalence of SUDs in chronic pain patents; the overlapping presentation of the two disorders; risk factors and stratification for addiction; identification of addiction in the chronic pain population; and suggestions for treating patients with COT, with an emphasis on relapse prevention. With appropriate assessment and treatment, COT for chronic pain patients with a history of SUD can be successful, leading to improved functionality and quality of life.

Keywords: Chronic pain, Chronic opioid therapy, Addiction/substance use disorder, Relapse prevention

Introduction

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Treating chronic pain with chronic opioid therapy (COT) in individuals with a history of a substance use disorder (SUD), whether active or in remission, presents a challenge to pain clinicians. This is, in part, due to concerns about the patient relapsing to active substance abuse in the course of COT, as analgesic treatment enables and legitimizes drug use for patients with SUDs [1-3]. In addition, clinicians may confuse "drug-seeking" behaviors with addictive disease, resulting in poor treatment outcomes such as premature discharge of patients from pain care [4]. Misconceptions persist as chronic pain patients with SUDs are often treated by clinicians who have insufficient training in addiction, and evidence-based clinical guidelines for managing pain while addressing SUDs are lacking [2,5]. The goal of chronic pain treatment in patients with SUDs is the same as that for patients without SUDs: specifically, to maximize functionality while providing pain relief. However, reluctance to prescribe opioids and poor understanding of the complex relationship between pain and addiction too often result in undertreated pain in this population [6].

A review of the literature reveals that no empirical studies have been conducted to investigate the risks and benefits associated with COT in chronic pain patients with a history of SUD [7]. This paper reviews what is known about the prevalence of SUDs in chronic pain patents; links between pain and addiction; risk factors and stratification for addiction and implications for COT; and indicators of addiction in this population. Suggestions for treating chronic pain in SUD patients receiving COT are outlined with an emphasis on the role of relapse prevention in successful outcomes.

Prevalence of SUDs in chronic pain patients

In attempting to estimate the prevalence or presence of SUD in chronic pain patients, terminology becomes important (Table 1). It is increasingly understood that SUD cannot be defined by *physical dependence* and *tolerance*, as these are predictable physiologic consequences of chronic opioid use. Reflecting this, in the *Diagnostic and Statistical Manual of Mental Disorders*, 5th Edition (DSM-V), tolerance and withdrawal are not counted as criteria for the substance use and addictive disorder diagnosis if a patient is taking an opioid analgesic under medical supervision [8].

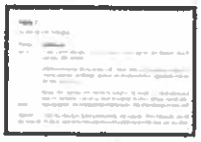

Table 1
Definition of terminology

Albeit using imperfect indicators, it has been estimated that the prevalence of opioid abuse in chronic pain patients ranges between 20-24% across health-care settings [17]. Using a survey approach and DSM-IV criteria, Boscarino and colleagues [18] completed phone interviews with a random sample of 705 chronic pain patients receiving COT in primary care and specialty pain treatment. They found that 26% of those reported a current opioid use disorder and 36% had a life-time opioid use disorder, findings that were replicated using DSM-V criteria [19]. A systematic review of literature synthesizing 21 studies published prior to February 2012 showed that the overall prevalence of current SUDs in chronic pain patients ranges from 3% to 48% depending on the population sampled [7]. The lifetime prevalence of any SUD ranged from 16% to 74% in patients visiting the emergency department, with those visiting for opioid refill having the highest rate. Further, it has been reported that 3.3% to 11.5% of chronic pain patients with a history of SUD may develop opioid addiction or abuse, whereas only 0.19% to 0.59% of those without a prior or current history of SUD develop the same [20].

Syndrome of pain and addiction

Chronic pain and addiction are best conceptualized as a syndrome. In some individuals with addictive disease, pain is identified as a factor contributing to their addiction. It has been hypothesized that untreated pain may be a risk factor for relapse for individuals with addiction in remission [21]; however, it has also been suggested that exposure to opioids in chronic pain patients with a history of SUD puts them at risk for opioid abuse and/or relapse [22].

Physiological and psychological aspects of active addictive disease can make pain more difficult to treat. Chronic use of opioid drugs appears to affect the processing of pain stimuli through sympathetic stimulation, hypothalamic-pituitary-adrenal axis dysregulation, and proinflammatory immune-system activation, resulting in increased sensitivity to pain or decreased pain tolerance [14,23]. These responses suggest that the presence of both chronic pain and opioid addiction may result in a reorganization of nociceptive pathways in the brain that subsequently cause increased pain perception, or so-called opioid-induced hyperalgesia.

Savage and Schofferman [24] described a "syndrome of pain facilitation" occurring in patients with untreated addiction and pain, such that the pain experience is worsened by the presence of addiction. Individuals who abuse alcohol, cocaine, opioids, or other drugs often experience alternating withdrawal and intoxication due to unstable

blood levels of drug. Similarly, for individuals receiving opioids, withdrawal can activate the sympathetic nervous system, with concomitant muscle tension, irritability, and dysphoria, further contributing to discomfort.

Mood, sleep, and personality disorders can aggravate pain symptoms and are frequently comorbid in patients with chronic pain [25-30]. The literature indicates that chronic pain patients with untreated depression respond poorly to pain treatment [31,32]. Due to functional limitations, chronic pain patients may become isolated and unable to engage in physical and social activities, which further contribute to the severity of the chronic pain experience [33,34]. Unable to fulfill work and domestic roles, they are also likely to experience interpersonal conflicts, financial difficulty, and poor social support, all of which are detrimental to adequate chronic pain management [35].

Similarly, mood disorders, including depression and anxiety, are common sources of distress in patients with SUD [36-38], which likewise diminish patient functionality [33]. The overall dysfunction associated with addiction contributes to distress and disability. Further, pain patients with active addition are unlikely to comply with nonopioid pain treatment regimens, including physical therapy and behavioral interventions. The signs and sequelae of untreated addiction thwart improvement with COT.

Unresolved emotional and social distress coupled with persistent pain may lead patients to self-medicate these uncomfortable feeling states with opioids. When self-medication becomes a coping mechanism, substance use can progress to a disorder, or cause relapse in patients with a history of SUD. In a recent study of 1334 patients receiving COT for noncancer chronic pain, those with moderate and severe depression were more likely to self-medicate nonpain symptoms with prescription opioids and to misuse their prescription opioid by self-increasing doses than were those without depression [39].

Risk factors and risk stratification for addiction in pain patients receiving COT

Clinicians should conduct a comprehensive risk assessment for opioid abuse or misuse when considering use of COT. The assessment should include known risk factors for addiction, including a personal or family history of substance abuse, childhood adverse events (eg, physical or sexual abuse, childhood neglect), psychiatric symptoms, and functional impairment (pain disability, sleep disturbance). With respect to pain symptoms, assessment in patients considered at risk for addictive disease must include careful delineation of the nociceptive and affective components of the pain syndrome; identification of associated factors that perpetuate pain; and identification of pain-related risk factors for opioid abuse and relapse. Degree of functionality (Table 2) in the presence of chronic pain is a critical assessment, as the effectiveness of COT is evident in this domain.

Table 2
Evidence of functional restoration [8]

Risk stratification approaches are indicated for selecting chronic pain patients for COT, and those with a history of SUD are considered at high risk for poor treatment response [40]. Being a chronic disease, it is critical to ensure that SUD's continue to be addressed while treating chronic pain. Gourlay, Heit, and Almahrezi [41] propose a 10-step universal precaution approach as a minimum standard of care for all chronic pain patients receiving COT (Table 3). This model of universal precautions is framed within a biopsychosocial approach and designed to reduce stigma, improve outcomes, and decrease risks associated with COT pain management for all patients [41], regardless of SUD history.

Table 3
Ten steps of universal precautions

Risk factors The risk factors for opioid abuse, misuse, or other aberrant drug-related behaviors in chronic pain patients receiving COT have been well-described, with a prior history of opioid abuse being the best predictor for both current and lifetime opioid use disorder in chronic pain patients [18,42]. Other important but less consistent risk factors for opioid abuse include pain-related functional limitations/impairments (including sleep disturbances); current cigarette smoking, a family history of substance abuse; a history of a mood disorder (eg, current post-traumatic disorder or depression); history of child sexual abuse or child neglect; involvement in the legal system; and significant psychosocial stressors [43-45]. Demographic correlates of opioid misuse in this patient population include age, gender, ethnicity, and employment status. Previous studies indicate that younger chronic pain patients (under age 65) are at higher risk for opioid abuse [18,46]. With respect to gender, women with chronic pain who reported more emotional issues and affective distress were at increased risk for opioid misuse, whereas men with legal problems tended to predict misuse prescription opioids [47].

Boscarino and colleagues [18] found that the chance of opioid abuse increases if a chronic pain patient has multiple risk factors, such that the odds ratio (OR) of a current opioid use disorder in chronic pain patients who present with four predictors (age, depression, psychotropic medication, and pain impairment) is 8.01. If the patient also has a history of severe opioid dependence and abuse, the risk of current opioid use disorder increased dramatically (OR, 56.36).

Risk stratification and monitoring strategies Atluri and colleagues [48] have suggested an algorithmic approach to prevent opioid abuse in chronic pain treatment by stratifying patients into high-, medium-, and low-risk groups using one of several validated screening tools (Figure 1). These tools include subjective questionnaires, eg, Screener and Opioid Assessment for Patients with Pain (SOAPP) [49], Pain Medication Questionnaire (PMQ) [50], and Prescription Drug Use Questionnaire Patient Version (PUDQP) [51]); and objective tools, eg, Addiction Behavior Checklist (ABC) [52], Diagnosis, Intractability, Risk, Efficacy (DIRE) [53], and Current Opioid Misuse Measure (COMM) [54].

Figure 1

Stratification of chronic pain patients by use of screening tools (cited in text) into high, medium, and low risk groups for opioid abuse, monitoring patients by using urine dug screening (UDS), Prescription Monitoring Programs (PMPs) and aberrant behaviors; ...

Based on the stratification of risk, different approaches are suggested. Individuals with a history of SUD are categorized as high risk, thus, frequent monitoring of medication use, urine drug testing (UDT) every three to six months, and reviewing Prescription Monitoring Program (PMP) reports every two to four months are recommended. Although not uniformly supported in the literature, these authors suggest that opioids should be avoided or prescribed only in low doses; a >50 mg morphine-equivalent dose should be used only rarely and only in specialized settings.

Building on the universal precautions, management can be tailored to the care for patients at risk for SUD. For example, in addition to the general components written in the opioid treatment agreement or contract, the clinician should stipulate that participation in ongoing addiction treatment (eg, 12-step meetings, outpatient treatment, or individual counseling/therapy) be required for COT prescription. More frequent office visits are required to better assess opioid use behaviors, opioid efficacy, and signs of relapse. Clinicians should prescribe opioids to these patients in smaller amounts, without refills, and conduct pill counts at each visit. If appropriate, a family member or a close friend can be included in the treatment plan (for example, to dispense medications).

Clinicians should collect urine samples more frequently for mass spectrometry confirmatory toxicology screen [55]. In a large prospective study of chronic pain patients receiving COT (N = 500), Manchikanti and colleagues

[56] found significant reductions in overall illicit drug use with adherence-monitoring procedures combined with random UDT. Continued monitoring using UDT significantly decreased the incidence of illicit drug use over time [57]. It is important to note that, although UDT is an objective measure of the presence of drugs and their metabolites, it is not a stand-alone indicator of adherence or addiction; thus, the results should be openly discussed with patients along with assessment of other indicators of relapse. False-positive and false-negative results can occur with UDT, so with unexpected findings, toxicology analyses should be verified and/or repeated.

Brief cognitive-behavioral interventions have been shown to reduce the risk of COT misuse in chronic pain patients. Using a randomized trial, Jamison and colleagues [58] tested the effects of combined close monitoring and cognitive behavioral treatment (education and motivational counseling) in patients at high risk for opioid misuse (due to a past history of addiction) in a pain management center. They found that no participant receiving cognitive-behavioral treatment was discharged due to aberrant behaviors, and that opioid treatment adherence and opioid misuse behaviors were better in this group than in those who did not receive the enriched treatment.

Identification of addiction in the chronic pain patient receiving COT

Savage and colleagues introduced the four "C" criteria for identifying opioid addiction in chronic pain population: impaired *c*ontrol over drug use, *c*ompulsive use, *c*ontinued use despite harm, and unmanageable drug *c*raving [10]. However, these criteria have not been validated in clinical settings. The multiple screening and assessment tools previously identified are helpful in identification, especially if compared with scores upon admission.

A strategy to distinguish between aberrant or misuse behaviors and addiction in chronic pain patients is to assess the relationship between opioid dose titration and functional restoration (Figure 2). In this approach, in response to aberrant "drug-seeking" behaviors (ie, continued complaints of pain and/or requests for more medication), the clinician increases the opioid dose in an effort to provide analgesia. Improvements in functional outcomes and quality of life, with fewer problematic behaviors, indicate that active addiction is not present. In this case, drug-seeking behaviors may reflect pseudo-addiction, therapeutic dependence, or opioid tolerance (Table 1). Effective dosing results in functional restoration.

Figure 2
Decision tree for interpreting aberrant prescription opioid use behavior in the chronic pain patients on opioid therapy. Adapted from [59,60].

Conversely, should overall functionality not improve with a dose increase, addiction is considered in the differential diagnosis. Listed in Figure 2 are alternate explanations for poor functional improvement, including non-opioid responsive pain; opioid-induced hyperalgesia; or an untreated psychiatric disorder. In these circumstances, clinicians should consider taper of the opioid dose and replace it with other pain-relief strategies [61] to improve function and quality of life. If the patient shows resistance to detoxification and cannot comply with the alternative treatment plan, addiction should be considered.

Treating chronic pain in SUD patients receiving COT

Patients with untreated addiction: focus on addiction treatment The authors strongly believe that patients with chronic pain and *active* addiction, regardless of type(s) of substance abused, are *not* candidates for COT [62]. Patients meeting DSM-V criteria for addiction and related disorders are, by definition, unable to achieve the goals of functional restoration. Untreated addiction results in poor functionality and, thus, will necessarily result in poor pain outcomes.

In many primary care or pain management settings, the ability to provide the comprehensive services necessary to treat patients with both pain and current addiction are sorely lacking. Patients with an active SUD should be referred to formal addiction treatment; thus, it is incumbent upon the prescribing clinician to have available a referral network of substance abuse treatment providers willing to collaborate on providing care to patients with comorbid pain and SUD. After referral, the pain clinician should continue to work closely with the SUD treatment provider to monitor use behaviors and pain outcomes.

Patients with addiction in remission: focus on relapse prevention For individuals with addiction in remission, the goal of treatment is the same as that as for all chronic pain patients: to improve pain and maintain functionality. Indicators of successful pain management include the patient's ability to comply with regimens; engage in cognitive-behavioral pain management strategies; utilize positive coping skills to manage stress; and establish better social support systems. Further, management of comorbid neuropsychiatric complications is critical to maximize functionality.

For many opioid addicts, disease remission includes opioid substitution therapy. In the context of managing pain in patients receiving methadone or buprenorphine for addiction, it is commonly assumed that the treatment opioid alone provides sufficient pain relief. Further, concerns that additional opioids put the patient at risk for untoward events, including respiratory depression and decreased level of consciousness [63], often limit opioid prescription. Although methadone and buprenorphine can be used to treat pain, their duration of analgesic action is shorter than effects on withdrawal and craving, thus dividing the daily dose and giving more frequently is the indicated strategy [64,65]. Further, patients on opioid substitution therapy develop some degree of opioid analgesic tolerance, and thus may require higher opioid doses to appreciate pain relief [40,66,67]. Studies have provided evidence that methadone maintenance patients may, in fact, have heightened pain sensitivity, and therefore have a higher opioid analgesic requirement than matched controls [68].

Regardless of the type(s) of substance previously abused, exposure to psychoactive medications can lead to relapse in patients with a recently or poorly treated SUD. Concerns of relapse may also contribute to clinicians' reluctance to prescribe COT for patients whose addiction is in remission. The literature provides evidence that patients with successfully treated addiction can be effectively treated with opioids for chronic pain [69]. Thus, when providing COT to these patients, in addition to maximizing functionality, the treatment goals include preventing an exacerbation of the SUD.

Central to this treatment is the integration of relapse prevention strategies into the plan of care. Relapse is a predictable event in the course of addictive disease and is understood to be a process that does not occur suddenly or spontaneously and is, therefore, preventable [70,71]. The well-known social-psychology model of relapse introduced by Marlatt and Gordon [72] almost 30 years ago suggests that relapse is part of the behavioral change process and relatively common as the patient attempts to integrate new and healthier self-management behaviors into his or her life. Substance use disorders are chronic diseases for which significant behavioral change is required to successfully achieve remission.

The relapse prevention model is depicted in Figure 3. A basic assumption of the model is that relapse events are preceded by encountering a *high-risk situation*, broadly defined as "a circumstance in which an individual's attempt to refrain from a particular behavior (ranging from any use of a substance to heavy or harmful use) is threatened" (p. 224) [73]. For patients with a history of SUD, triggers for relapse are attributed to both intrapersonal and interpersonal stressors. For patients with chronic pain, unique stressors include the losses and limitations associated with chronic pain and pain-related diminished quality of life. Although some high-risk situations (eg, negative affect, craving) seem to be universal across addictive behaviors, they vary across individuals and may change within the same individual over time [74].

Figure 3

The cognitive-behavioral model of the relapse process posits a central role for high-risk situations and for the SUD patient's coping response to those situations. People with effective coping responses to high-risk situations (i.e., increased ...

Whether or not a high-risk situation results in relapse is determined by the individual's ability to engage an effective coping response to the stressor [71]. In the model, *positive outcome expectancies* and the *abstinence violation effect* are important cognitive factors in determining relapse probability. Positive-outcome expectancies refer to the anticipated positive effects of substance use (eg, getting "high," decreasing anxiety, social rewards), which override memories of the consequences associated with use. The abstinence violation effect refers to the patient viewing a single lapse, or "slip," as a personal failure, leading to feelings of guilt, demoralization, and hopelessness with respect to his or her ability to maintain change. More recent conceptualizations of relapse describe it as a dynamic phenomenon, and a complex nonlinear process in which various factors act jointly and interactively to influence relapse timing and severity [73].

Central to successful relapse prevention are learned cognitive and behavioral strategies the patient can employ in the face of high-risk situations. These strategies are of two broad categories: (1) a specific intervention technique designed to assist the individual in anticipating and effectively coping with high-risk situations; and (2) global self-control approaches designed to reduce relapse risk by promoting positive lifestyle changes. In that high-risk situations vary among individuals, it is critical to conduct a comprehensive assessment of substance use patterns, high-risk situations, coping skills, self-efficacy, outcome expectancies, and readiness to change, as well as to document coexisting conditions that may complicate the relapse-prevention process. To increase insight into, and self-monitoring of, problematic behaviors, the patient is encouraged to identify immediate precipitants and distal lifestyle factors related to relapse and to evaluate his or her own coping responses to high-risk situations.

Specific intervention strategies include enhancing self-efficacy by setting achievable behavioral goals and purposeful dispelling of positive outcome expectancies. With respect to global self-control strategies, patients are encouraged to incorporate stress-reduction activities into their daily life, such as exercise or meditation. The overall purpose is lifestyle balancing, which increases self-efficacy across life domains and therefore minimizes the risk of relapse.

Relapse-prevention strategies for SUD patients receiving COT

Preventing relapse is central to effective COT in patients with SUD in remission. Clinicians must continuously assess the patient's relative risk for it and monitor for its emergence. Further, the ability to manage a relapse episode, if one should occur, is a necessary skill of the COT prescriber. With addiction in remission, optimal functioning with appropriate opioid use can be appreciated.

Assessment of risk of relapse A series of questions should be asked of the chronic pain patient regarding the status of SUD remission (Table 4). Asking these questions at each visit allows for early identification of high-risk situations and potential coping responses to these stressors.

Table 4

Questions to assess risk for relapse

Recognition of and monitoring for relapse The identification of relapse in chronic pain patients receiving COT is complicated by their tendency to hide problematic use for the fear of losing access to medications. A careful

monitoring plan including general and additional precautions (as described above) is critical. A relapse contract can be developed with the patient in early treatment, which is individualized to the patient and specifies steps or actions that will be taken by both the patient and clinician if relapse occurs. The patient's behaviors with respect to the opioid-analgesic regimen provide the best evidence for the presence of active addiction. Evidence of relapse in chronic pain patients includes the presence of adverse consequences associated with opioid use, a loss of control over the use of opioids, preoccupation with obtaining opioids, and a lack of improvement in function [10].

An objective indicator of medication use is adherence to a treatment contract or medication agreement, which clearly outlines acceptable and unacceptable medication use behaviors. However, engaging in unacceptable medication-taking behaviors cannot be considered a definitive indicator of addictive disease, and rather may reflect an untreated psychiatric disorder or misunderstanding of dosing instructions. Similarly, unexpected UDT results may indicate patients' nonadherence to opioid regimen or problematic use of medications, but it is not a specific indicator of relapse to addictive disease. Thus, clinicians should not summarily discharge SUD patients from COT based on behavioral indicators or UTD results; neither are specific to exacerbation of addiction. Rather, these findings should prompt a dialogue between the patient the clinician. Patients with a history of SUD who are nonadherent to the prescribed opioid regimen should be strongly encouraged to increase recovery efforts, and their access to opioids should be more tightly controlled. Evaluation by an addiction specialist is warranted if behaviors do not quickly resolve.

Management of relapse If relapse is identified, it is critical to continue to support patients' efforts towards recovery and maintain high levels of controls over opioid access. If attempted, opioid detoxification should be gradual so as not to elicit opioid withdrawal symptoms (usually, no more than a 20-25% dose reduction every two days). It is important not to characterize the relapse as a treatment failure but to frame it as a part of the process of recovery from an addictive disease and successful pain treatment.

Studies indicate that exposure to specific high-risk situations alone does not predict relapse, but the way in which people cope with those situations is a strong predictor of subsequent relapse or continued abstinence [76-78]. Following a relapse, a careful review of the relapse episode can be helpful. This analysis should chronicle the relapse and identify associated emotional and cognitive status that preceded it. Doing so will help the patient better recognize his/her own vulnerability to relapse as well as coping strategies that may or may not be effective.

If relapse is identified, discharging the patient from pain treatment without providing addiction intervention is not only premature, but sets the patient up for the progression of addictive disease. It is important that clinicians who prescribe COT for chronic pain are prepared with a relapse management strategy and have addiction expertise or support in place. It is critical that COT providers maintain a thoughtful and working partnership with addiction treatment providers so that pain treatment can continue while supporting addiction remission. As opposed to discharge, it is incumbent upon the pain-management practitioner to take more of an advocacy role in the management of addiction.

Conclusion

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Management of chronic pain in patients with a history of SUD with COT can be challenging, but with appropriate assessment and management, can be successful, leading to enhanced functionality and quality of life. Albeit imperfect, data suggest that up to one-quarter of chronic pain patients have an SUD history. The interrelated behavioral symptomatology of addiction and chronic pain suggests that the untreated presence of one precludes effective treatment of the other. Demographic correlates and risk factors for SUD have been well-described, and COT management is most successful when based upon risk stratification with increased control of opioid access for those classified as high risk.

The evidence is good that COT can be effective in patients with chronic pain whose SUD is in remission,

suggesting that a primary goal of treatment, in addition to improving pain and maximizing functionality, is to prevent a relapse or exacerbation of addictive disease. Expanding the pain treatment plan to include specific relapse-prevention strategies and directed relapse management, if needed, is critical to appreciate the benefits of COT for patients with a history of SUD. Identifying relapse in this population can be challenging and should not be based on a single indicator. Premature discharge of the SUD patient from pain treatment provides an opportunity for addiction to worsen. It is suggested that the best chronic pain outcomes occur when the pain clinician and addiction treatment provider work in concert using a syndromal approach to treat pain and addiction.

Competing interests

Go to:

The authors declare that they have no competing interests.

Authors' contributions

Go to:

YPC and PC collaborated on the conception of the manuscript and YPC wrote the first draft. Both authors read, edited and approved the final manuscript.

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BARBARA BOWERS, MD, PLLC
INNOVATIVE OPHTHALMOLOGY
1130 Lone Oak Rd
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(270) 415-0245

My name is Dave Hoffman. I am the administrator for Innovative Ophthalmology. Innovative Ophthalmology is an ophthalmic practice that specializes in cataract and refractive surgery. It is located in Paducah and is owned by Barbara Bowers M.D.

Thank you for the opportunity to comment on the proposed changes to the state health plan.

Ophthalmology is unique in many ways.
Ophthalmology is the only medical specialty that is allowed to perform a non-covered procedure as part of a covered procedure. This makes them unique from any other medical specialty. For example when a patient receives a joint replacement they do not have the ability to pay more for an upgraded artificial joint. You simply follow the advice of the surgeon and receive what is covered by Medicare, Medicaid and other insurance companies. In ophthalmology, there are a number of options available to upgrade your surgical procedure. You may choose laser technology to assist in the removal of your cataract and correct your astigmatism. You may also upgrade your lens implant to one that corrects astigmatism or one that allows you to see both distance and near. All of these options are available and have an additional cost that is 100% the responsibility of the patient. Medicare, Medicaid and third party payers will only cover the basic surgical procedure and a standard lens implant.

This point is critical when we look at the Secretary's goal of readily adopting technology to increase high quality health services. History has shown that surgery centers in Kentucky that are not owned by ophthalmologists are hesitant to invest in ophthalmic laser technology. The reason is simple and based on economics. Medicare prohibits surgery centers from seeking reimbursement for use of ophthalmic laser technology.

This creates a financial dilemma for surgery centers. Without a revenue stream to offset the cost of very expensive laser ophthalmic technology they are choosing not to purchase technology that has proven to promote faster healing times and better visual outcomes. There are less then a handful of eye surgeons who have invested the large sums of money necessary to bring this technology to Kentucky.

Anti kickback statutes prohibit surgery centers from inducing surgeons to operate at a specific surgery center. Since a select few surgeons now own the technology, problems arise in how these surgeons can legally house their technology in a surgery center owned by someone else. There is currently a surgeon in Kentucky who purchased advanced laser technology when both the hospital owned ASC and a privately owned ASC decided not to purchase the technology. This surgeon is required to rent space in a surgery center to house the technology for which they paid hundreds of thousands of dollars. This is not equitable and is a barrier for the expansion of advanced ophthalmic laser technology.

The proposed changes to the State Health Plan would not include ophthalmologists who have already invested or want to invest in advanced laser eye technology.

The cabinet has proposed the following change:

> Notwithstanding criteria 1 and 2, an application to establish an ASC shall be consistent with this Plan if the following conditions are met:
>
> 1. The applicant is a private office of a physician or a physician group, 100% owned by physicians, organized and in continuous operation in Kentucky for a period of ten (10) years prior to the date the application was submitted;
>
> 2. The applicant documents that the proposed outpatient surgery procedures have been performed in the private office for a period of five (5) years prior to the date the application was submitted;
>
> 3. The proposed ASC is located in the county where the private office is currently located;
>
> 4. Only one (1) ASC shall be establish by the applicant; and;
>
> 5. The applicant documents that existing surgical service is accredited by the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF), Accreditation Association for Ambulatory Health Care (AAAHC), American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP), or The Joint Commission (TJC).

(ophthalmology agrees that the proposed limiters as described in numbers 1,3,4, and 5 are necessary to achieve the Secretaries goal of offering a discreet office exemption)

An ophthalmologist who has purchased or is considering purchasing ophthalmic laser technology is excluded from this exemption **because they are unable to use the technology in their office. It is simply not the standard of care.**

We propose the following language or something similar be added to the above highlighted paragraph #2 of the proposed changes to the State Health Plan:

OR the applicant documents they are an ophthalmologist or ophthalmology practice who within five (5) years prior to the date the application was submitted, has invested no less than three hundred thousand dollars ($300,000.00) in advanced ophthalmic laser technology. The applicant shall be granted a single specialty CON limited to ophthalmic surgical procedures.

We feel this language accomplishes many of the goals articulated by the Secretary at the joint Health and Welfare Committee meeting in June. The proposed language:

- Encourages the adoption of ophthalmic laser technology that has been proven to promote faster healing times and improved visual outcomes.
- Allows for revenue to offset the cost of ophthalmic laser technology, thus insuring the financial stability of physician owned ASC's.
- Strikes an equitable balance between competition and quality. The single specialty restriction would prohibit ophthalmic surgeons from competing with other surgery centers while increasing access to ophthalmic laser technology that improves the quality of care.
- Creates a discreet exemption. There are currently only a few surgeons in Kentucky that have invested in this advanced ophthalmic laser technology that would qualify for this exemption.

Currently in Kentucky not one ophthalmologist is employed by a hospital. Yet the hospitals and other CON stakeholders hold tremendous power over ophthalmologists who are early adopters of technology and want to ensure Kentucky stays on the cutting edge of ophthalmic care.

We respectfully ask that you include the proposed language in the revised State Health Plan. This will allow pioneering ophthalmologists the opportunity to provide greater access to advanced ophthalmic laser technology.

If you have any questions or concerns regarding this proposed change to the State Health Plan please feel free to contact me at any time

Sincerely,

Dave Hoffman
Administrator
Innovative Ophthalmology
1130 Lone Oak Rd.
Paducah, KY 42003
O: 270-415-0245 C: 270-210-9355

BARBARA BOWERS, MD, PLLC
INNOVATIVE OPHTHALMOLOGY
1130 Lone Oak Rd
Paducah, KY 42003
(270) 415-0245

My name is Barbara Bowers M.D. I am the owner of Innovative Ophthalmology. Innovative Ophthalmology is an ophthalmic practice that specializes in cataract and refractive surgery. It is located in Paducah.

Thank you for the opportunity to comment on the proposed changes to the state health plan.

The proposed physician office exemption states:

5. Notwithstanding criteria 1 and 2, an application to establish an ASC shall be consistent with this Plan if the following conditions are met:

    1. The applicant is a private office of a physician or a physician group, 100% owned by physicians, organized and in continuous operation in Kentucky for a period of ten (10) years prior to the date the application was submitted;

I have a concern that a narrow interpretation of the word "continuous" may exclude physicians that the cabinet has no intent to exclude. Several situations come to mind. Would a physician who chooses to take extended maternity leave or has taken an extended disability leave no longer be considered to be in continuous operation? Also the words "private office of" could narrowly be interpreted as the same office. Does the above language mean that a physician who has not worked for the same group or employer has not been in continuous operation? There are a large number of physicians who have been organized and have been continuously practicing medicine in Kentucky, however, they may have changed employers or groups. They may have actually practiced in different regions of the Commonwealth. These physicians have certainly shown their commitment to practicing medicine in Kentucky. Perhaps there is a way to clarify the language to ensure physicians in these situations are not excluded. The following is a possible solution:

    1. The applicant is a physician or a physician group, 100% owned by physicians, that has been organized and practicing medicine in Kentucky for a period of ten (10) years prior to the date the application was submitted;

The field of Ophthalmology should be considered in these proposed changes. Ophthalmology is unique in many ways.

Ophthalmology is the only medical specialty that is allowed to perform a non-covered procedure as part of a covered procedure. This makes them unique from any other medical specialty. For example when a patient receives a joint replacement they do not have the ability to pay more for an upgraded artificial joint. You simply follow the advice of the surgeon and receive what is covered by Medicare, Medicaid and other insurance companies. In ophthalmology, there are a number of options available to upgrade your surgical procedure. You may choose laser technology to assist in the removal of your cataract and correct your astigmatism. You may also upgrade your lens implant to one that corrects astigmatism or one that allows you to see both distance and near. All of these options are available and have an additional cost that is 100% the responsibility of the patient. Medicare, Medicaid and third party payers will only cover the basic surgical procedure and a standard lens implant.

This point is critical when we look at the Secretary's goal of readily adopting technology to increase high quality health services. History has shown that non- ophthalmologist owned surgery centers in Kentucky are hesitant to invest in ophthalmic laser technology. The reason is simple and based on economics. Medicare prohibits surgery centers from seeking reimbursement for use of ophthalmic laser technology.

This creates a financial dilemma for surgery centers. Without a revenue stream to offset the cost of very expensive laser ophthalmic technology they are choosing not to purchase technology that has proven to promote faster healing times and better visual outcomes. There are less then a handful of eye surgeons who have invested the large sums of money necessary to bring this technology to Kentucky.

Anti kickback statutes prohibit surgery centers from inducing surgeons to operate at a specific surgery center. Since a select few surgeons now own this ophthalmic laser technology, problems arise in how these surgeons can legally house their technology in a surgery center owned by someone else. There is currently a surgeon in Kentucky who purchased advanced laser technology when both the hospital owned ASC and a privately owned ASC decided not to purchase the technology. This surgeon is required to rent space in a surgery center to house the technology for which they paid hundreds of thousands of dollars. This is not equitable and is a barrier for the expansion of advanced ophthalmic laser technology.

The proposed changes to the State Health Plan would not include ophthalmologists who have already invested or want to invest in advanced laser eye technology.

The cabinet has proposed the following change:

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3. The proposed ASC is located in the county where the private office is currently located;

4. Only one (1) ASC shall be establish by the applicant; and;

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(ophthalmology agrees that the proposed limiters as described in numbers 1,3,4, and 5 are necessary to achieve the Secretaries goal of offering a discreet office exemption)

An ophthalmologist who has purchased or is considering purchasing ophthalmic laser technology is excluded from this exemption **because they are unable to use the technology in their office. It is simply not the standard of care.**

We propose the following language or something similar be added to the above highlighted paragraph #2 of the proposed changes to the State Health Plan:

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We feel this language accomplishes many of the goals articulated by the Secretary at the joint health and welfare committee meeting in June. The proposed language:

- Encourages the adoption of ophthalmic laser technology that has been proven to promote faster healing times and improved visual outcomes.

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- Strikes an equitable balance between competition and quality in outpatient care. The single specialty restriction would prohibit ophthalmic surgeons from competing with other surgery centers while increasing access to ophthalmic laser technology that improves the quality of care.
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Sincerely,

Barbara Bowers M.D.
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O: 270-415-0245
C: 270-210-8893

Please see written comments submitted by a prominent eye surgeon from Paducah, KY. I have been made aware of their interest and involvement on this issue through my service as Chairman of the Senate Health and welfare committee. Please take note of their submission and if you have any questions, please do not hesitate to contact me.

Sincerely,

Julie Raque Adams

Julie Raque Adams
State Senator

My name is Dave Hoffman. I am the administrator for Innovative Ophthalmology. Innovative Ophthalmology is an ophthalmic practice that specializes in cataract and refractive surgery. It is located in Paducah and is owned by Barbara Bowers M.D.

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> 3. The proposed ASC is located in the county where the private office is currently located;

4. Only one (1) ASC shall be establish by the applicant; and;

5. The applicant documents that existing surgical service is accredited by the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF), Accreditation Association for Ambulatory Health Care (AAAHC), American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP), or The Joint Commission (TJC).

(ophthalmology agrees that the proposed limiters as described in numbers 1,3,4, and 5 are necessary to achieve the Secretaries goal of offering a discreet office exemption)

An ophthalmologist who has purchased or is considering purchasing ophthalmic laser technology is excluded from this exemption **because they are unable to use the technology in their office. It is simply not the standard of care.**

We propose the following language or something similar be added to the above highlighted parapraph #2 of the proposed changes to the State Health Plan:

OR the applicant documents they are an ophthalmologist or ophthalmology practice who within five (5) years prior to the date the application was submitted, has invested no less than three hundred thousand dollars ($300,000.00) in advanced ophthalmic laser technology. The applicant shall be granted a single specialty CON limited to ophthalmic surgical procedures.

We feel this language accomplishes many of the goals articulated by the Secretary at the joint Health and Welfare Committee meeting in June. The proposed language:

- Encourages the adoption of ophthalmic laser technology that has been proven to promote faster healing times and improved visual outcomes.
- Allows for revenue to offset the cost of ophthalmic laser technology, thus insuring the financial stability of physician owned ASC's.

- Strikes an equitable balance between competition and quality. The single specialty restriction would prohibit ophthalmic surgeons from competing with other surgery centers while increasing access to ophthalmic laser technology that improves the quality of care.
- Creates a discreet exemption. There are currently only a few surgeons in Kentucky that have invested in this advanced ophthalmic laser technology that would qualify for this exemption.

Currently in Kentucky not one ophthalmologist is employed by a hospital. Yet the hospitals and other CON stakeholders hold tremendous power over ophthalmologists who are early adopters of technology and want to ensure Kentucky stays on the cutting edge of ophthalmic care.

We respectfully ask that you include the proposed language in the revised State Health Plan. This will allow pioneering

ophthalmologists the opportunity to provide greater access to advanced ophthalmic laser technology.

If you have any questions or concerns regarding this proposed change to the State Health Plan please feel free to contact me at any time

Sincerely,

Dave Hoffman

Administrator

Innovative Ophthalmology

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Paducah, KY 42003

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JOHN-KENYON
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June 30, 2015

***via* EMAIL (tricia.orme@ky.gov)**

Cabinet for Health and Family Services
Office of Legal Services
ATTN: Tricia Orme
275 East Main Street 5 W-B
Frankfort, Kentucky 40621

RE: State Health Plan Comments

Dear Ms. Orme:

My name is E. Britt Brockman MD. I am the owner of John-Kenyon Eye Center. I have been practicing in Kentucky for 23 years. Our center currently has 18 locations in Kentucky and is an ophthalmic practice that specializes in cataract and refractive surgery, as well as retina, cornea and glaucoma. As a practice, John-Kenyon prides itself on staying at the forefront of medical technology. John-Kenyon's physicians perform both LASIK and Cataract surgery with the highest quality laser technology and believe that combining experience with the most advanced technology provides patients with the best care possible. Thank you for the opportunity to comment on the proposed changes to the state health plan.

The proposed changes to the State Health Plan would not permit ophthalmologists who have already invested in or want to invest in advanced laser eye technology to establish an ASC. The Cabinet has proposed the following new review criteria for ASCs:

6. Notwithstanding criteria 1 and 2, an application to establish an ASC shall be consistent with this Plan if the following conditions are met:

a. The applicant is a private office of a physician or a physician group, 100% owned by physicians, organized and in continuous operation in Kentucky for a period of ten (10) years prior to the date the application was submitted;

b. The applicant documents that the proposed outpatient surgery procedures have been performed in the private office for a period of five (5) years prior to the date the application was submitted;

c. The proposed ASC is located in the county where the private office is currently located;

d. Only one (1) ASC shall be establish by the applicant; and

e. The applicant documents that existing surgical service is accredited by the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF), Accreditation Association for Ambulatory Health Care (AAAHC), American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP), or The Joint Commission (TJC).

An ophthalmologist who has purchased or is considering purchasing ophthalmic laser technology is excluded from this exemption **because they are unable to use the technology in their office and, as a result, do not satisfy criterion b., listed above**. It is simply not the standard of care for ophthalmologists who use laser technology for procedures to provide the services in their offices. So, while the applicant will be able to document that it has been providing the proposed outpatient surgery procedures for a period of five (5) years prior to the date the application was submitted, it will not be able to prove that these procedures were provided in an office setting.

We propose the following language or something similar be added to the above highlighted paragraph b. of the proposed changes to the State Health Plan:

OR

The applicant documents that it has been providing the proposed outpatient surgery procedures for a period of five (5) years prior to the date the application was submitted and that the applicant is an ophthalmologist or ophthalmology practice who within five (5) years prior to the date the application was submitted, has invested no less than three hundred thousand dollars ($300,000.00) in advanced ophthalmic laser technology and has been using the laser to provide the proposed outpatient surgery procedures. The applicant shall be granted a single specialty CON limited to ophthalmic surgical procedures.

We feel this language accomplishes many of the goals articulated by the Secretary at the joint health and welfare committee meeting in June. The proposed language:

- Encourages the adoption of ophthalmic laser technology that has been proven to promote faster healing times and improved visual outcomes;
- Allows for revenue to offset the cost of ophthalmic laser technology, thus insuring financially stable physician-owned ASC's;

- Strikes an equitable balance between competition and quality in outpatient care. The single specialty restriction would prohibit ophthalmic surgeons from competing with other surgery centers while increasing access to ophthalmic laser technology that improves the quality of care; and
- Creates a discreet exemption. There are currently only a few surgeons in Kentucky that have invested in this advanced ophthalmic laser technology that would qualify for this exemption.

The field of Ophthalmology should be considered when revising the ASC review criteria. Ophthalmology is unique in many ways.

Ophthalmology is the only medical specialty that is allowed to perform a non-covered procedure as part of a covered procedure. For example when a patient receives a joint replacement they do not have the ability to pay more for an upgraded artificial joint. You simply follow the advice of the surgeon and receive what is covered by Medicare, Medicaid and other insurance companies. In ophthalmology, there are a number of options available to upgrade your surgical procedure. Specifically, patients may choose laser technology to assist in the removal of your cataract and correct your astigmatism. Patients may also upgrade their lens implant to one that corrects astigmatism or one that allows you to see both distance and near. All of these options are available and have an additional cost that is 100% the responsibility of the patient. Medicare, Medicaid and third party payers will only cover the basic surgical procedure and a standard lens implant.

This point is critical when we look at the Secretary's goal of readily adopting technology to increase high quality health services. History has shown that non-ophthalmologist owned surgery centers in Kentucky are hesitant to invest in ophthalmic laser technology. The reason is simple and based on economics. Medicare prohibits surgery centers from seeking reimbursement for use of ophthalmic laser technology. This creates a financial dilemma for surgery centers. Without a revenue stream to offset the cost of very expensive laser ophthalmic technology they are choosing not to purchase technology that has proven to promote faster healing times and better visual outcomes. There are less than a handful of eye surgeons who have invested the large sums of money necessary to bring this technology to Kentucky.

Anti-kickback statutes prohibit surgery centers from inducing surgeons to operate at a specific surgery center. Since a select few surgeons now own this ophthalmic laser technology, problems arise in how these surgeons can legally house their technology in a surgery center owned by someone else. There is currently a surgeon in Kentucky who purchased advanced laser technology when both the hospital owned ASC and a privately owned ASC decided not to purchase the technology. This surgeon is required to rent space in a surgery center to house the technology for which they paid hundreds of thousands of dollars. This is not equitable and is a barrier for the expansion of advanced ophthalmic laser technology.

Hospitals and other CON stakeholders hold tremendous power over ophthalmologists who are early adopters of technology and want to keep Kentucky on the cutting edge of ophthalmic care. We respectfully ask that you include this proposed language in the revised State Health Plan. This will allow pioneering ophthalmologists the opportunity to provide greater access to advanced ophthalmic laser technology and to bring Kentucky to the forefront when it comes to medical technology in the field of ophthalmology.

If you have any questions or concerns regarding this proposed change to the State Health Plan, please feel free to contact me at any time. I welcome to the opportunity to sit down and discuss this further. My contact information is listed directly below.

E. Britt Brockman MD
4040 Dutchmans Avenue
Louisville, KY 40207
Cell: 502-553-5444

Sincerely,

E. Britt Brockman